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#2  
12/12/01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and  
Scott Siegel

Application No.: 09/927,703 Group Art Unit: 1642

Filed: August 10, 2001 Examiner: Not Assigned

Title: ANTI-TNF ANTIBODIES AND PEPTIDES OF HUMAN TUMOR NECROSIS  
FACTOR



CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231	
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INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
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(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☐ Copies of the cited references are enclosed.
- ☒ Copies of cited references are enclosed except those entered in prior applications, U.S. Application No. 09/756,398 and Application No. 09/133,119, to which priority under 35 U.S.C. 120 is claimed. The earlier applications contains copies of the cited references.
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ the enclosed English language abstract.
- ☒ Applicant requests that the following pending applications be considered:

Examiner's  
Initials

U.S. Patent Application No. 09/756,398, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 8, 2001, Docket No.: 0975.1005-006

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U.S. Patent Application No. 09/756,161, by Junming Le, Jan Vilcek, Peter Daddona,  
John Ghrayeb, David M. Knight and Scott Siegel, filed January 8, 2001, Docket No.:  
0975.1005-007

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U.S. Patent Application No. 09/756,301, by Junming Le, Jan Vilcek, Peter Daddona,  
John Ghrayeb, David M. Knight and Scott Siegel, filed January 8, 2001, Docket No.:  
0975.1005-008

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Examiner

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Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☒ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. 09/756,398, to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

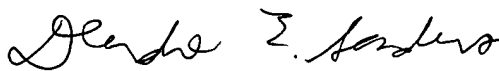
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- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
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Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By

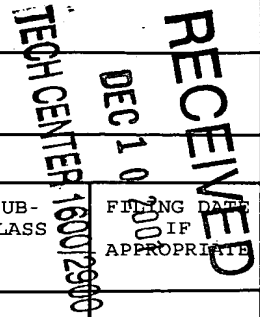
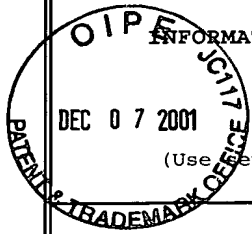


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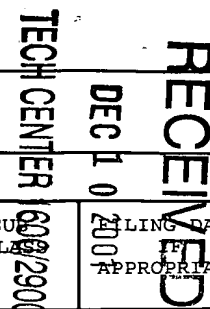
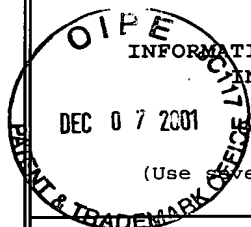
Concord, Massachusetts 01742-9133

Dated: *October 29, 2001*

PTO-1449 REPRODUCED				ATTORNEY DOCKET NO. 0975.1005-013		APPLICATION NO. 09/927,703	
INFORMATION DISCLOSURE CITATION IN AN APPLICATION October 29, 2001 (Use several sheets if necessary)				APPLICANT Junming Le, et al.			
				FILING DATE August 10, 2001		GROUP 1642	
U.S. PATENT DOCUMENTS							
EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	4,603,106	07/29/86	Cerami et al.	435	7	
	AB	4,822,776	04/18/89	Cerami et al.	514	21	
	AC	5,658,570	08/19/97	Newman et al.	424	184.1	
	AD	5,750,105	5/12/98	Newman et al.	424	133.1	
	AE	5,231,024	7/27/93	Moeller et al.	435	240.27	
	AF	5,888,511	03/30/99	Skurkovich et al.	424	145.1	
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	AH	5,993,833	11/30/99	DeLacharriere et al.	424	401	
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	AJ	6,190,691 B1	02/20/01	Mak	424	449	
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	AL	0212489A2	04 MAR 87	EPO			
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	AN	0288088A2	26 OCT 88	EPO			
	AO	0308378A2	22 MAR 89	EPO			
	AP	0380068A1	01 AUG 90	EPO			
	AQ	0393438A3	24 OCT 90	EPO			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AR	Beutler, B. et al., "Identity of tumour necrosis factor and the macrophage-secreted factor cachectin," <i>Nature</i> , 316:552-554 (1985).					
	AS	Beutler, B. et al., "Passive Immunization Against Cachectin/Tumor Necrosis Factor Protects Mice from Lethal Effect of Endotoxin," <i>Science</i> , 229:869-871 (1985).					
	AT	Morrison, Sherie L., "Transfectomas Provide Novel Chimeric Antibodies," <i>Science</i> , 229:1202-1207 (1985).					
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	AN2	0433900A1	26 JUN 91	EPO			
	AO2	0526905A2	10 FEB 93	EPO			
	AP2	WO91/02078	21 FEB 91	PCT			
	AQ2	WO92/07076	30 APR 92	PCT			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AU	Liang, Chi-Ming et al., "Production and Characterization of Monoclonal Antibodies Against Recombinant Human Tumor Necrosis Factor/Cachectin," <i>Biochem. &amp; Biophys. Res. Comm.</i> , 137(2):847-854 (1986).					
	AV	Hirai, Makoto et al., "Production and characterization of monoclonal antibodies to human tumor necrosis factor," <i>J. of Immun. Methods</i> , 96:57-62 (1987).					
	AW	Piguet, Pierre-Francois et al., "Tumor Necrosis Factor/Cachectin is an Effector of Skin and Gut Lesions of the Acute Phase of Graft-vs.-Host Disease," <i>J. Exp. Med.</i> , 166:1280-1289 (1987).					
	AX	Meager, Anthony et al., "Preparation and Characterization of Monoclonal Antibodies Directed Against Antigenic Determinants of Recombinant Human Tumour Necrosis Factor (rTNF)," <i>Hybridoma</i> , 6(3):305-311 (1987).					
	AY	Fendly, Brian M. et al., "Murine Monoclonal Antibodies Defining Neutralizing Epitopes on Tumor Necrosis Factor," <i>Hybridoma</i> , 6(4):359-370 (1987).					
	AZ	Bringman, Timothy S. and Aggarwal, Bharat B., "Monoclonal Antibodies to Human Tumor Necrosis Factors Alpha and Beta: Applications for Affinity Purification, Immunoassays, and as Structural Probes," <i>Hybridoma</i> , 6(5):489-507 (1987).					
	AR2	Tracey, Kevin J. et al., "Anti-cachectin/TNF monoclonal antibodies prevent septic shock during lethal bacteraemia," <i>Nature</i> , 330:662-664 (1987).					
	AS2	Nagai, M. et al., "Antibody to tumor necrosis factor (TNF) reduces endotoxin fever," <i>Experientia</i> , 44:606-607 (1988).					
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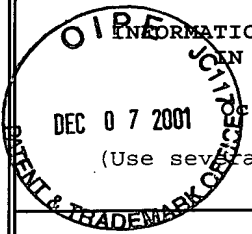


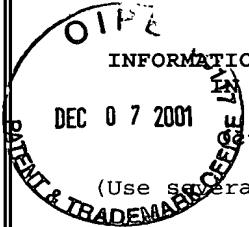
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		FILING DATE August 10, 2001		GROUP 1642			
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U.S. PATENT DOCUMENTS							
EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
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	AN3	91/09967	11 JUL 91	PCT			
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	AT2	Shimamoto, Yoshinori et al., "Monoclonal antibodies against human recombinant tumor necrosis factor: prevention of endotoxic shock," <i>Immunology Letters</i> , 17:311-318 (1988).					
	AU2	Di Giovine, Francesco, S. et al., "Tumour necrosis factor in synovial exudates," <i>Annals of the Rheumatic Diseases</i> , 47:768-772 (1988).					
	AV2	Collins, M.S. et al., "Immunoprophylaxis of Polymicrobial Cellulitis with a Human Monoclonal Antibody Against Lipopolysaccharide Antigen of <i>Pseudomonas aeruginosa</i> ," Abstract E-63, <i>Abstracts of Annual Meeting 1989</i> .					
	AW2	Exley, A.R. et al., "Monoclonal Antibody (Mab) to Recombinant Human Tumour Necrosis Factor (rhTNF) in the Prophylaxis and Treatment of Endotoxic Shock in Cynomolgus Monkeys," <i>Medical Research Society</i> , Abstract 184, p. 50 (1989).					
	AX2	Cross, A.S. et al., "Pretreatment with Recombinant Murine Tumor Necrosis Factor $\alpha$ /Cachectin and Murine Interleukin 1 $\alpha$ Protects Mice from Lethal Bacterial Infection," <i>J of Exp Med.</i> , 169:2021-2027 (1989).					
	AY2	Engelmann, Hartmut et al., "A Tumor Necrosis Factor-binding Protein Purified to Homogeneity from Human Urine Protects Cells from Tumor Necrosis Factor Toxicity," <i>J. of Bio. Chem.</i> , 264(20):11974-11980 (1989).					
	AZ2	Kawasaki, Hajime et al., "Analysis of Endotoxin Fever in Rabbits by Using a Monoclonal Antibody to Tumor Necrosis Factor (Cachectin)," <i>Infection and Immunity</i> , 57(10):3131-3135 (1989).					
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	AN4	WO 92/16553	19 MAR 92	PCT			
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	AR3	Fong, Yuman et al., "Antibodies to Cachectin/Tumor Necrosis Factor Reduce Interleukin 1 $\beta$ and Interleukin 6 Appearance During Lethal Bacteremia," <i>J. Exp. Med.</i> , 170:1627-1633 (1989).					
	AS3	Von Asmuth, E.J.U. et al., "Tumour Necrosis Factor Alpha (TNF- $\alpha$ ) and Interleukin 6 in a Zymosan-Induced Shock Model," <i>Scand. J. Immunol.</i> , 32:313-319 (1990).					
	AT3	Herve, P. et al., "Monoclonal Anti TNF $\alpha$ Antibody for the Treatment of Severe Acute GvHD in Humans," Abstract 3.25, <i>Lymphoma Res.</i> 9:591 (1990).					
	AU3	Silva, Ayona T. et al., "Prophylactic and Therapeutic Effects of a Monoclonal Antibody to Tumor Necrosis Factor- $\alpha$ in Experimental Gram-Negative Shock," <i>J. of Infectious Diseases</i> , 162:421-427 (1990).					
	AV3	Opal, Steven M. et al., "Efficacy of a Monoclonal Antibody Directed Against Tumor Necrosis Factor in Protecting Neutropenic Rats from Lethal Infection with <i>Pseudomonas aeruginosa</i> ," <i>J. of Infectious Diseases</i> , 161:1148-1152 (1990).					
	AW3	Tavernier, Jan et al., "Analysis of the Structure-Function Relationship of Tumour Necrosis Factor. Human/Mouse Chimeric TNF Proteins: General Properties and Epitope Analysis," <i>J. Mol. Biol.</i> , 211:493-501 (1990).					
	AX3	Lucas, R. et al., "Generation and characterization of a neutralizing rat anti-rm TNF- $\alpha$ monoclonal antibody," <i>Immunology</i> , 71:218-223 (1990).					
	AY3	Hinshaw, L.B. et al., "Survival of Primates in LD <sub>100</sub> Septic Shock Following Therapy with Antibody to Tumor Necrosis Factor (TNF $\alpha$ )," <i>Circulatory Shock</i> , 30:279-292 (1990).					
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	AO4	0 867 509 A2	30 SEP 98	EPO			
	AP4	0 861 850 A1	02 SEP 98	EPO			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AZ3	Nophar, Yaron et al., "Soluble forms of tumor necrosis factor receptors (TNF-Rs). The cDNA for the type 1 TNF-R, cloned using amino acid sequence data of its soluble form, encodes both the cell surface and a soluble form of the receptor," <i>The EMBO Journal</i> , 9(10):3269-3278 (1990).					
	AR4	Engelmann, Hartmut et al., "Two Tumor Necrosis Factor-binding Proteins Purified from Human Urine," <i>J. of Bio. Chem.</i> , 265(3):1531-1536 (1990).					
	AS4	Verhoef, J. and Torensma, R., "Prospects for Monoclonal Antibodies in the Diagnosis and Treatment of Bacterial Infections," <i>Eur. J. Clin. Microbiol. Dis.</i> , 9(4):247-250 (1990).					
	AT4	Loetscher, Hansruedi et al., "Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor," <i>Cell</i> , 61:351-359 (1990).					
	AU4	Schall, Thomas J. et al., "Molecular Cloning and Expression of a Receptor for Human Tumor Necrosis Factor," <i>Cell</i> , 61:361-370 (1990).					
	AV4	Akama, Hideto et al., "Mononuclear Cells Enhance Prostaglandin E <sub>2</sub> Production of Polymorphonuclear Leukocytes via Tumor Necrosis Factor $\alpha$ ," <i>Biochemical and Biophysical Research Comm.</i> , 168(2):857-862 (1990).					
	AW4	Exley, A.R. et al., "Monoclonal antibody to TNF in severe septic shock," <i>The Lancet</i> , 335:1275-1277 (1990).					
	AX4	Möller, Achim et al., "Monoclonal Antibodies to Human Tumor Necrosis Factor $\alpha$ : In Vitro and In Vivo Application," <i>Cytokine</i> , 2(3):162-169 (1990).					
	AY4	Ruddle, Nancy H. et al., "An Antibody to Lymphotoxin and Tumor Necrosis Factor Prevents Transfer of Experimental Allergic Encephalomyelitis," <i>J. Exp. Med.</i> , 172:1193-1200 (1990).					
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	AQ4	0 869 179 A1	07 OCT 98	EPO			
	AL5	0 870 827 A2	14 OCT 98	EPO			
	AM5	0 706 795 A2	17 APR 96	EPO			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AZ4	Galloway, Cynthia J. et al., "Monoclonal anti-tumor necrosis factor (TNF) antibodies protect mouse and human cells from TNF cytotoxicity," <i>J. of Immunological Methods</i> , 140:37-43 (1991).					
	AR5	Waldmann, Thomas A., "Monoclonal Antibodies in Diagnosis and Therapy," <i>Science</i> , 252:1657-1662 (1991).					
	AS5	Aderka, Dan et al., "The Possible Role of Tumor Necrosis Factor (TNF) and Its Natural Inhibitors, The Soluble-TNF Receptors, In Autoimmune Diseases," <i>Israel J. Med. Sci.</i> , 28(2):126-130 (1992).					
	AT5	Pennington, James, "TNF: Therapeutic Target in Patients with Sepsis," <i>ASM News</i> , 58(9):479-482 (1992).					
	AU5	Harris, William J. and Emery, Steven, "Therapeutic antibodies - the coming of age," <i>TBTECH</i> , 11:42-44 (1993).					
	AV5	Parrillo, Joseph E., "Pathogenetic Mechanisms of Septic Shock," <i>N.E. Journal of Medicine</i> , 328(20):1471-1477 (1993).					
	AW5	Aggarwal, Bharat B. et al., "Human Tumor Necrosis Factor Production, Purification and Characterization," <i>J. of Biol. Chem.</i> , 260(4):2345-2354 (1985).					
	AX5	Beutler, B. et al., "Purification of Cachectin, A Lipoprotein Lipase-Suppressing Hormone Secreted by Endotoxin-induced RAW 264.7 Cells," <i>J. Exp. Med.</i> , 161:984-995 (1985).					
	AY5	Echtenacher, Bernd et al., "Requirement of Endogenous Tumor Necrosis Factor/Cachectin for Recovery from Experimental Peritonitis," <i>J. of Immunology</i> , 145(11):3762-3766 (1990).					
	AZ5	Smith, Craig R., "Human and Chimeric Antibodies to LPS and TNF," 4Abstract, <i>Endotoxemia &amp; Sepsis Conference</i> (1991).					
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	AN5	0 706 795 A3	17 DEC 97	EPO			
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	AR6	Bodmer, Mark, "Humanized Antibodies for Anti-TNF Therapy," Abstract, <i>Endotoxemia &amp; Sepsis Conference</i> (1991).					
	AS6	Genebank Accession, No. N90300 (1989, November 1).					
	AT6	Genebank Accession, No. M32046 (1990, June 15).					
	AU6	Paulus, H., "Preparation and Biomedical Applications of Bispecific Antibodies", <i>Behring Inst. Mitt</i> , No. 78:118-132 (1985).					
	AV6	Partsch, G., et al., "Upregulation of Cytokine Receptors sTNF-R55, sTNF-R75, and sIL-2R in Psoriatic Arthritis Synovial Fluid," <i>J. of Rheumatology</i> , 25:1 105-110 (1998).					
	AW6	Omulecki, A., et al., "Is Pentoxifylline Effective in the Treatment of Psoriasis?", <i>J. of the Am. Academy of Dermatology</i> , 34:4 714-715.					
	AX6	Sagawa, Y., et al., "Is Sustained Production of Tumor Necrosis Factor- $\alpha$ Relevant to the Development of Pustular Psoriasis?," <i>Dermatology</i> , 187:81-83 (1993).					
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